

REMARKS

Rejections under 35 U.S.C. § 102(b)

The Office Action states that claims 6-16 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Takata et al. (Cardiovascular Research, 32, 286-293, 1996). Applicants respectfully traverse the rejection.

As basis for the rejection of claims 6-16, the Office Action alleges that: “Takata et al. teach a *pharmaceutical composition* that comprises an effective amount of synthetic alpha human atrial natriuretic peptide, which increases the level of cyclic guanosine monophosphate, and has cardioprotective effects on myocardial ischemia and reperfusion injury.” However, claims 6-10 are directed to a *method* of treatment or prophylaxis and claims 11-16 are directed to a *method* for reducing an infarct region or suppressing enlargement of an infarct region. Accordingly, Applicants respectfully submit that the allegation that Takata et al. teaches a pharmaceutical composition provides no basis for rejection of claims 6-16 which are directed to methods. For at least the foregoing reasons, Applicants respectfully traverse the rejections of claims 6-16.

The Office Action alleges that “Takata’s method anticipates claims 6-10 of [the] instant application.” As basis for this allegation, the Office Action states that:

Takata et al. [teaches] a method of cardioprotection (claim 6) of myocardial ischemia [(claim 8)] and reperfusion injury [(claim 7)] by administering a composition comprising an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) (claim 6, 9 and 10), which increases the level of cyclic guanosine monophosphate (cGMP) (claim 6), and has cardioprotective effects on myocardial ischemia and reperfusion injury (claims 6, 7, 8).

In contrast to the present invention, the cardioprotective effects on myocardial ischemia and reperfusion injury of ANP disclosed in Takata et al. are limited to the suppression of arrhythmia such as ventricular extrasystoles and the suppression of the decrease of intra-cellular high-energy

phosphates. Claim 6--and claims 7-10, which are dependent therefrom--recites a method of treatment "which has an effect of reducing an infarct region." This novel discovery is further described in the specification wherein it is stated that: "The inventors of the present invention further studied the properties of natriuretic peptides, and found for the first time that these peptides can reduce an infarct region occurring in a model of acute myocardial infarction involving ischemia reperfusion." (Specification, p. 3, ll. 19-23) In contrast to this claimed and recited discovery of the present invention, nothing is described or even remotely suggested in Takata et al. to the effect that ANP can reduce an infarct region occurring in an acute myocardial infarction involving ischemia reperfusion, which is the unexpected effect of the present invention. More specifically, Takata et al. merely mention, as results of administration of exogenous ANP, that:

- (1) plasma cGMP levels increased by 8-fold;
- (2) the prevalence and frequency of ventricular extrasystoles within 10 minutes after reperfusion markedly decreased;
- (3) no dog in the ANP group had ventricular fibrillation;
- (4) ATP content in the inner layers of the ischemic myocardium in the ANP group was higher than in controls; and
- (5) there was no significant difference in the content of myocardial tissue angiotensin II between the groups. (Abstract of Takata et al.)

As such, Applicants respectfully submit that the effects achieved by the present invention, as recited in claims 6-10, are clearly distinguishable from any effects disclosed by Takata et al.

With regard to claims 11-16 of the present invention, the Office Action does not recite any basis for the rejection under 35 U.S.C. § 102(b), nor does it refute Applicants' previous traversal of these rejections of claims 11-16. Applicants enter a continued traversal of the rejections of claims 11-16 and maintain that claims 11-16 distinguish over Takata et al. In the alternative, Applicants respectfully request further elaboration as to the reasoning behind the continued anticipation rejection of claims 11-16 so that Applicants may better address an alleged basis for these rejections.

For at least the foregoing reasons, Applicants respectfully submit that the present invention distinguishes over Takata et al. Accordingly, Applicants respectfully request removal of the rejections of claims 6-16 under 35 U.S.C. § 102(b).

CONCLUSION

In view of the above remarks, early notification of a favorable consideration is respectfully requested. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned, at the telephone number listed below, to conduct an interview in an effort to expedite prosecution in connection with the present application. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-0206.

Respectfully submitted,

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